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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/017,697

12/07/2001

Joyce Bedelia B. Santos

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12/30/2003

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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 12/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/017,697

Applicant(s)

B. SANTOS ET AL.

Examiner

Blessing M. Fubara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-42 is/are allowed.
- 6) ☒ Claim(s) 1-20, 22-24, 26 and 28-33 is/are rejected.
- 7) ☒ Claim(s) 21, 25, 27 and 34 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Examiner acknowledges receipt of remarks to election requirement filed 10/04/03.

Election Requirement

The requirement in the action mailed on 09/10/03 is a requirement for election of species and not a restriction. However, the election requirement is withdrawn. All pending claims 1-46 are examined.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 7, 8, 10, 11, 13, 15-19, 22-24, 26, 28-33 and 43-46 are rejected under 35 U.S.C. 102(b) as being anticipated by White (US 5,431,916).

White discloses a composition comprising a pharmaceutical, tri-ester, polyvinylpyrrolidone (abstract) and optionally polyethylene glycol having molecular weight of from about 300 to about 4,600 (column 6, lines 41-51 and column 7, lines 1 and 2). Few of the pharmaceutically active compounds in White's invention are analgesics, anti-inflammatory agents, anti-pyretics, calcium channel blockers, beta-blockers and expectorants and antitussives (column 5, lines 25-62); and specific examples are acetaminophen, ketoprofen, naproxen, ibuprofen, pseudoephedrine, dextromethorphan, guaifenesin, doxylamine, phenylpropanolamine, chlorpheniramine, antibiotics, antivirals and caffeine and pharmaceutically acceptable salts and

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mixtures thereof (column 5, line 63 to column 6, line 7). The composition formulated as solution is buffered to pH of about 7 (column 8, lines 5-12). The composition may further contain glycerin, sorbitan, sorbitol (column 8, line 60), colorings, flavorings, preservatives, antioxidants and essences (column 9, lines 11 and 12). Polyvinylpyrrolidone ranges from 17.14 to 29.36% in examples III to VIII and in column 4, lines 52-56; the polyvinylpyrrolidone is disclosed to be present from about 10% to about 50%. The pharmaceutical is present from about 0.01-50%. Instant claim 15 recites the intended use of the composition and in a composition claim a future intended use is not critical. The comprising language of the instant claims does not exclude the presence of the tri-ester from the instant claimed composition. The instant method recited in claim 43 merely combines the ingredients to form the composition disclosed in the prior art. The teaching disclosed in White meets the limitations of the claims.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 5, 6 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 5,431,916).

White teaches the instant composition as discussed above except that White fails to teach the amount of polyethylene glycol. However, White discloses that polyethylene glycol may be employed to facilitate the solubility of actives or modify the viscosity of suspensions (column 7, lines 24-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time

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the invention was made to use an appropriate amount of polyethylene glycol. One having ordinary skill in the art would have been motivated to modify the composition of White by using an amount of polyethylene glycol in the composition with the expectation that the resulting composition will have the desired viscosity.

5. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 5,431,916).

White teaches the instant composition except that the amount of polyvinylpyrrolidone in White's composition is greater than 7%. However, White discloses that polyvinylpyrrolidone is a solubilizing or suspending agent in combination with the tri-ester. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use an amount of polyvinylpyrrolidone that is less than the amount used in the composition of the prior art. One having ordinary skill in the art would have been motivated to modify the composition of the prior art by employing polyvinylpyrrolidone in amounts that will provide in which the ingredients of the composition are appropriately suspended to yield the expected liquid composition.

6. Claims 12 and 20 rejected under 35 U.S.C. 103(a) as being unpatentable over White (US 5,431,916).

White discloses the instant composition except that White fails to disclose the amount of sweetening agents recited in instant claim 12. Regarding instant claim 20, the specific antibiotics recited are encompassed in the generic antibiotic teaching disclosed in the prior art. Since sweetening agents are known to be used to mask the taste of bitter tasting medicines such as acetaminophen, it would be necessary to use an appropriate amount of the sweetening agent

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that will mask the taste. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the composition of White with an amount of sweetening agent to mask the taste of acetaminophen, say. One having ordinary skill in the art would have been motivated to modify White's composition by employing sweetening agent in amounts that would be expected to mask the taste of bitter tasting medicines.

7. Claims 21, 25, 27 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art does not disclose composition comprising the drugs recited in claims 21, 25, 27 and 34.

Allowable Subject Matter

8. Claims 35-42 are allowable because the prior art does not disclose the specific compositions recited therein.

9. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

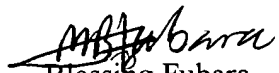
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name.

Blessing Fubara
Patent Examiner
Tech. Center 1600